

## Guidance: Plan Submission of P&T Committee Member List and Certification Statement

This document summarizes CMS policy on Part D Applicant/Sponsor and PBM submission of P&T Committee membership, and the accountability that each Part D Applicant/Sponsor holds regarding the integrity of the P&T Committee whose membership is submitted either directly by the Part D Applicant/Sponsor or by the applicant/sponsor's PBM. This document also instructs Part D Applicants (or their PBM's) on how to submit the Applicant's P&T Committee membership list, and a Certification of P&T Integrity and Quality in the event the Applicant is planning to operate under a confidentiality agreement with its PBM (such that the PBM does not disclose the membership to the Applicant).

### P&T Committee Member Disclosure to CMS

As provided in CFR 423.120 (b)(1) of the final regulation for the Medicare drug benefit, a Part D Sponsor's P&T Committee list must contain a majority of members who are practicing physicians and/or pharmacists, include at least one practicing physician and one practicing pharmacist who are experts regarding care of the elderly or disabled individuals, and includes at least one practicing physician and one practicing pharmacist who are independent and free of conflict relative to the Part D Sponsor or Plan and pharmaceutical manufacturers.

In the event the Part D Applicant/Sponsor has entered into a confidential agreement such that the PBM will not disclose its P&T Committee membership to the Part D Applicant/Sponsor, then it is the Part D Sponsor's responsibility to notify CMS that this information will be submitted by the Sponsor's PBM. Moreover, the Part D Applicant/Sponsor must ensure that the PBM notifies CMS of the P&T Committee membership. Also, the Part D Applicant/Sponsor should ensure that the PBM notifies the Sponsor that this information has been successfully submitted to CMS.

As one check on the integrity of the P&T Committee membership, CMS intends to submit member names to the HHS Office of the Inspector General Exclusion List database for verification that the members are not on this list. CMS requires that Part D Applicant/Sponsor to remove any P&T member identified on the OIG Exclusion List from the P&T Committee immediately for the purposes of the Part D benefit. Failure to resolve this issue could result in a delay in awarding a Sponsor's Part D contract with CMS.

## P&T Committee Integrity and Certification of Such by Part D Applicant Sponsor

CMS does expect the Part D Applicant/Sponsor to have a reasonable policy in place to confirm the integrity, expertise, and qualification of its respective P&T committee. Moreover, Part D Applicants/Sponsors of the Part D benefit are accountable to CMS for the integrity, qualifications, and expertise of the PBM's P&T committee.

In the event CMS identifies a problem with a member of a P&T Committee, the Part D Applicant/Sponsor will be notified by CMS of such a problem, and the Sponsor must assure that the PBM takes appropriate steps to correct the problem. During CMS' efforts to resolve the issue, CMS cannot guarantee that the name of the P&T member in question will not be shared with the Part D Sponsor. Non-compliance with P&T Committee requirements is a potential breach of the Part D Applicant/Sponsor's application requirements/contract with CMS, and resolution of this matter may require that CMS provide the Applicant/Sponsor specific information about the PBM's P&T committee. For a Part D Applicant/Sponsor that does not comply with the Part D program's P&T Committee requirements, the Applicant/Sponsor could have the offer of a CMS contract delayed, and could be subject to a corrective action plan and sanctions, depending on the nature of the problem. Of course, CMS will in no event share the names of P&T committee members with parties other than the particular Part D Sponsor with whom the PBM has contracted and/or governmental officials as may be necessary to resolve a Part D compliance matter.

Furthermore, as required under Section 3.1.1.F.12 of a Part D Applicant PDP solicitation (and Section 3.1.1.D.12 of the MA-PD and Cost Plan solicitations), Sponsor's PBM contract must contain a provision that assures that for any activity the Part D plan delegates to its sub-contractor, such activity or responsibility may be revoked if CMS or the Part D Applicant/Sponsor determines that the PBM is not performing satisfactorily. The Part D Applicant/Sponsor contract with the PBM may include other remedies in lieu of revocation to address this requirement.

## Instructions to Plans and PBMs

**A.** In the event that Part D Applicant failed to submit a complete P&T Committee members list with the March 23, 2005 Part D Benefit Application, Part D Applicant must complete the attached table for submission to CMS by April 13, 2005. Applicant should follow the mailing instructions listed below.

**B.** If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant must complete the attached Certification by April 13, 2005. Applicant should follow the mailing instructions listed below.

C. If the Part D Applicant sub-contracts with a PBM for its P&T Committee and operates under a Confidentiality Agreement (such that its members are not disclosed to the Part D Applicant) then the Applicant is responsible to forward the attached P&T Committee Member Disclosure form to sub-contracted PBM and direct the PBM to submit the form to CMS by April 13, 2005. PBM should follow the mailing instructions below.

D. In the event of any future changes to the membership of the Part D Sponsor's P&T Committee or the PBM's P&T Committee, Part D Sponsors must (or in the case of a confidential agreement the Part D Sponsor must assure that the PBM) notify the appropriate CMS account manager (to be assigned at a future date) within 30 days of the effective date of such change.

## Mailing Instructions

1. Provide a signed cover sheet indicating that the information being sent to CMS is an addendum to the Plan's Part D Application.
2. Please mail 4 CD's containing both the completed P&T Committee Member Disclosure form and the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form.
3. Please mail 4 hard copies, including one original, of both the completed P&T Committee Member Disclosure form and the completed Certification for Part D Sponsors Using a Pharmacy Benefit Manager's Pharmacy and Therapeutics Committee under a Confidentiality Agreement form.

Mail the CD's and hard copy material via courier to:  
Centers for Medicare and Medicaid Services  
ATTN: Marietta Mack/Addendum to Generalist Review Section/ (P&T Member List)  
and/or (P&T Certification)  
Mail Stop S1-25-13 Location S2-04-05  
7500 Security Boulevard  
Baltimore, MD 21244-185

Please do not resubmit entire hard copy application or entire CD's. Only submit the portions of the application that are requested above.

## PHARMACY AND THERAPEUTICS COMMITTEE MEMBER DISCLOSURE

Name of Part D Plan or PBM: \_\_\_\_\_

If Part D Plan, provide Part D Contract number(s): \_\_\_\_\_

Contact Person: \_\_\_\_\_

Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

A. Complete the table below.

<b>PROVIDE THE NAMES OF THE MEMBERS OF YOUR ORGANIZATION'S P&amp;T COMMITTEE. INDICATE WHICH MEMBERS ARE PRACTICING PHYSICIANS OR PRACTICING PHARMACISTS. FURTHER, INDICATE WHICH MEMBERS ARE EXPERTS IN THE CARE OF THE ELDERLY OR DISABLED, AND FREE OF ANY CONFLICT OF INTEREST WITH YOUR ORGANIZATION AND PHARMACEUTICAL MANUFACTURERS. (APPLICANTS SHOULD MARK THE INFORMATION AS PROPRIETARY.) ADD ADDITIONAL ROWS AS NECESSARY</b>					
	<b>Practice/Expertise</b> <i>Mark an 'X' in Appropriate Column</i>			<b>Free of Any Conflict of Interest</b> <i>Type Yes or No</i>	
Full Name of Member	Practicing Physician	Practicing Pharmacist	Elderly/Disabled Expert	With You're Organization?	With Pharmaceutical Manufacturers?

B. Complete the table below if a PBM submitting on behalf of Part D plan.

<b>PROVIDE THE NAMES OF THOSE APPLICANTS FOR THE PART D BENEFIT THAT YOUR ORGANIZATION IS PROVIDING PHARMACY BENEFIT MANAGEMENT SERVICES, THE TYPE OF APPLICATION, AND THE CONTRACT NUMBER(S). ADD ADDITIONAL ROWS AS NECESSARY.</b>		
Organization Name	Type of Application	Contract Number(s)

**CERTIFICATION FOR PART D SPONSORS USING A PHARMACY BENEFIT  
MANAGER'S PHARMACY & THERAPEUTICS COMMITTEE UNDER A  
CONFIDENTIALITY AGREEMENT**

A. I, the undersigned, certify, on behalf of LEGAL NAME OF PART D SPONSOR  
APPLICANT ("Applicant"), to the following:

- 1) I certify that APPLICANT has entered into a contract with LEGAL NAME OF  
PBM ("PBM") to perform pharmacy benefit management services related to the  
operation of a Medicare Part D benefit plan(s) on behalf of APPLICANT.
- 2) I agree, to the best of my knowledge, that "PBM," has a Pharmacy and  
Therapeutics (P&T) Committee that contains a majority of members who are  
practicing physicians and/or pharmacists, includes at least one practicing  
physician and one practicing pharmacist who are experts regarding the care of the  
elderly or disabled individuals, and includes at least one practicing physician and  
one practicing pharmacist who are independent and free of conflict relative to my  
plan and organization and pharmaceutical manufacturers.
- 3) I agree that the PBM will supply to CMS the following information, including  
but not limited to, the full legal name of each member of its P&T Committee  
designated as a practicing physician or pharmacist specializing in elderly and/or  
disabled care. Each member must also disclose any conflict of interest with my  
organization, and/or pharmaceutical manufacturers.
- 4) I agree that my organization will establish by September 15, 2005, policies and  
procedures to ensure and confirm the ongoing integrity, qualifications and  
expertise of the PBM's P&T Committee.
- 5) I agree that in the event CMS identifies a problem with a member of the PBM's  
P&T Committee, my organization will be notified by CMS of such a problem. In  
such an instance, my organization must assure that the PBM takes appropriate  
steps to correct the problem or risk being subject to a corrective action plan and  
sanctions, depending on the nature of the problem.

B. I agree that CMS may inspect the records and premises of my organization or  
my subcontractor to ensure compliance with the statements to which I have  
attested above.

C. I certify that I am authorized to sign on behalf of the Applicant.

Part D Plan Contract Number: \_\_\_\_\_

\_\_\_\_\_  
Authorized Representative Name (printed)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Authorized Representative Signature

\_\_\_\_\_  
Date (MM/DD/YYYY)